REMARKS/ARGUMENTS

In response to the Final Office Actions mailed April 1, 2011 and February 18, 2011, Applicants propose to amend their application and request reconsideration in view of the proposed amendments and the following remarks. In this amendment, Claim 6 is proposed to be amended, no new claims have been added and claims 9 and 10 were previously cancelled without prejudice so that Claims 6-8 remain pending. No new matter has been introduced.

Claims 6-7 were rejected as being unpatentable over U.S. Patent Publication No. 2005/0065596 to Tseng et al. (Tseng) in view of Windecker et al. (Current Pharmaceutical Design) and U.S. Patent Application Publication No. 2005/0106203 to Roorda et al. (Roorda). Claim 8 was rejected as being unpatentable over Tseng in view of Windecker and Roorda and further in view of U.S. Patent Publication No. US 2002/0013616 to Carter et al. (Carter). These rejections are respectfully traversed.

In order to make a finding of obviousness, an Examiner must (1) determine the scope and content of the prior art, including non-analogous art if it is in the field of endeavor reasonably related to the particular problem to which the claimed invention is directed, (2) ascertain the differences between the claimed invention and the prior art, considering both the prior art and claimed invention as a whole, and (3) resolve the level of ordinary skill in the art at the time of the invention, factoring in the creativity that one of ordinary skill in the art would employ as well as the Examiner's own knowledge and technical expertise.

It is respectfully submitted that the references taken as a whole fail to disclose or suggest all of the claimed limitations.

Tseng discloses trichostatin A. Windecker discloses the use of rapamycin. Roorda discloses the blends of polymers. Carter discloses stents. Focusing on Roorda, one can see that there are two inventions disclosed therein. One to an implantable medical device coated with a therapeutic agent and the other to an implantable medical device coated with a polymer or blend of polymers with the therapeutic agent contained therein. Roorda also specifically discloses the creation of a single layer of a blend of a fluoropolymer and an acrylate. This is not two single layers as claimed in the present invention.

In making the rejection, the Examiner asserts that Tseng discloses trichostatin A, rapamycin and drug depots formed from polymers. The Examiner also asserts that Windecker discloses rapamycin and polymers. Finally, the Examiner asserts that Roorda discloses a drug and polymer basecoat, a topcoat for drug elution control and that one can use both acrylates and fluoropolymers.

Applicants have reproduced paragraphs 28 and 29 below with emphasis to clearly show that Roorda discloses blending polymers to create a new polymer. In the claimed invention; however, there is no blending as clearly claimed. For all the reasons stated herein, there can be no obiousness question.

[0028] Examples of other polymers with which polyacrylates can be blended include fluorinated polymers, such as poly(vinylidene fluoride) (PVDF) and poly(vinylidene fluo-ride-co-hexafluoro propene) (PVDF-HEP). **The blend of a polyacrylate and a fluorinated**

polymer can contain between about 10 and about 95% (mass) of the fluorinated polymer.

[0029] The polyacrylates can be used to manufacture the primer layer, drug-polymer layer, topcoat membrane, or all three layers. For example, the polyacrylates can be used to make both the drug-polymer layer and the topcoat membrane, but not the primer layer. Any combination of the three layers can include a polyacrylate, so long as at least one of the layers includes the material. If a polyacrylate is used to make only one of the layers, the other layer or layers can be made of an alternative polymer.

Claim 6 claims a medical device comprising an implantable structure; a basecoat layer affixed to the implantable structure, the basecoat layer comprising a first polymeric material; trichostatin A, in thereapeutic dosages, releasably affixed to the implantable structure for the treatment of restenosis following vascular injury, the trichostatin A being incorporated into the basecoat layer, the concentration of trichostatin A being less than 100 nano molar; rapamycin, in therapeutic dosages, releasably affixed to the implantable structure for the treatment of restenosis following vascular injury, the rapamycin being incorporated into the basecoat layer, the rapamycin and the trichostatin A potentiating each others effectiveness; and a separate and distinct topcoat layer comprising a second polymeric material affixed to the basecoat layer to control the elution rate of the trichostatin A and the rapamycin, the topcoat layer comprising the second polymeric material and the basecoat layer comprising the first polymeric material being immiscible and chemically incompatible polymeric materials, wherein the first polymeric material includes a copolymer polyvinylidenefluoride-co-hexafluoropropylene and the

second polymeric material includes at least 150 micrograms of poly(n-butylmethacrylate) layer, wherein the basecoat and the topcoat are affixed as separate and distinct layers upon each other and configured to create a chemical and physical barrier to elution of the rapamycin and the trichostatin A. None of the references, whether taken alone or in combination disclose or suggest the unique invention of amended independent claim 6. More specifically, the references ail to disclose or suggest all of the claimed elements in combination with distinct polymer layers to create physical and chemical barriers to drug elution. As indicated above, Roorda discloses blends as set forth in all his examples. In the present invention, the layers of polymers are distinct, there are no blends. All of the references teach multiple polymer systems for separate use. They are alternatives. The present invention uses dissimilar polymers on the same device. **No reference found teaches using a fluropolymer and an acrylate polymer in the same device and not as a blend in the unique structure claimed for the claimed purpose.** As claim 8 depends from claim 6, the same arguments apply. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

A favorable action on the merits is earnestly solicited.

Respectfully submitted,

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